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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,629	09/29/2003	Hector F. DeLuca	1256-00923	2546

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/673,629	<b>Applicant(s)</b> DELUCA ET AL.	
	<b>Examiner</b> San-ming Hui	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1-22-2004</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The application is a divisional application of 09/616,164.

Applicant's preliminary amendments filed September 29, 2003 have been entered. Cancellation of claims 1-17 and 23-29 is acknowledged.

Claims 18-22 are pending.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca et al (US Patent 5,843,928).

Deluca et al. teaches a genus of vitamin D compounds including 2-methylene-19-nor-20(S)-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub>, an exemplified compound, as useful in treating leukemia, colon cancer, breast cancer and prostate cancer (See claim 32, also col. 4, lines 43-47). Deluca et al. also teaches the vitamin D compounds therein, in a dosage of 0.01 to 100mcg/day as useful in treating leukemia, colon cancer, breast cancer and prostate cancer (See col. 4, lines 43-52).

Deluca et al. does not specifically teach 2-methylene-19-nor-20(S)-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub> as useful in treating leukemia, colon cancer, breast cancer and prostate cancer.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 2-methylene-19-nor-20(S)-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub>, in the herein claimed dosage, in a method of treating leukemia, colon cancer, breast cancer and prostate cancer.

One of ordinary skill in the art would have been motivated to employ 2-methylene-19-nor-20(S)-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub>, in the herein claimed dosage, in a method of treating leukemia, colon cancer, breast cancer and prostate cancer. It is known that the vitamin D compounds of Deluca as useful to treat leukemia, colon cancer, breast cancer and prostate cancer. Possessing teachings of Deluca et al., one of skilled artisan would have motivated to employ any of the vitamin D compounds of Deluca et al., including 2-methylene-19-nor-20(S)-1 $\alpha$ ,25-dihydroxyvitamin D<sub>3</sub>, in the method of treating leukemia, colon cancer, breast cancer and prostate cancer.

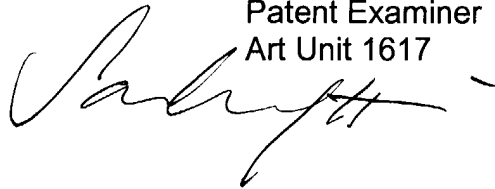
Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui  
Patent Examiner  
Art Unit 1617

A handwritten signature in black ink, appearing to read 'San-ming Hui', is written over the printed name and title.